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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 522,342	03 09 2000	Timothy A. Stewart	A-68670 RMS DAV	3273

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 03 11 2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/522,342

Applicant(s)

STEWART ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-26 and 28-77 is/are pending in the application.
- 4a) Of the above claim(s) 23-26 and 28-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 13-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Status of the claims

1. Claims 12 and 27 have been cancelled as requested in the amendment of Paper No.5.

Claims 1-11, 13-26, 28-77 are pending in the instant application.

Election/Restrictions

2. Applicant's election without traverse of Group I in Paper No. 15 is acknowledged.

Claims 23-26 and 28-77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 15.

Claims 1-11 and 13-22 are under examination in the instant office action.

Oath/Declaration

3. Clarification of inventorship in the instant application is requested. Also, clarification of the citizenship of A. Goddard is requested.

Specification

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (page 19, line 5). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

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5. Table 1 of pages 32-60 is found undecipherable. Clarification of the content and its relation to the instant specification is requested.

6. The use of the trademarks has been noted in this application (page 28, line 31; page 86, line 30; page 90, line 18; page 109, line 22; page 118, line 13; page 123, line 13; page 120, line 28). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicant is advised to carefully check the specification for other possible embedded hyperlinks or trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 14-16 and 18-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic molecule of SEQ ID NO:1 encoding a FGF-19 polypeptide, does not reasonably provide enablement for any other isolated nucleic acid molecule encoding a FGF-19 polypeptide specifically articulated in claims 1, 5, 7, 13, 15, 18-22. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1, 14-16 and 18-22 are directed to nucleic acid molecules encoding a FGF-19 polypeptide. The instant specification discloses FGF-19 as a novel polypeptide of SEQ ID NO:2 as derived from the coding sequence of SEQ ID NO:1 (page 14, lines 28-29). The examples provided in the specification identify the asserted biological activity of FGF-19. However, the claims 1, 14-16 and 18-22 are drawn to isolated nucleic acid molecules that have at least about 80% sequence identity to DNA molecules encoding a FGF-19 polypeptide, thereby requiring undue experimentation to discover how to make the full scope of Applicant's invention, as currently claimed. The instant specification fails to disclose other nucleic acid molecules that have at least about 80% sequence identity to SEQ ID NO:1 and possess the function of FGF-19 of SEQ ID NO:1. There is no indication in the specification which would lead to conclusion which portion of SEQ ID NO:1 is responsible for the growth factor function of SEQ ID NO:1. The prior art does not teach that a nucleic acid that has at least about 80% identity to a nucleic acid encoding a growth factor would encode a polypeptide that retains the biological activity of the original growth factor. The working examples provided in the instant specification support only FGF-19, a polypeptide encoded by SEQ ID NO:2. Thus, in view of the lack of teachings and unpredictability of the art set forth earlier, and also the total absence of the working examples, the instant specification while being enabling for the isolated nucleic acid molecule of SEQ ID NO:1 encoding FGF-19 polypeptide is not found to be enabling for an isolated nucleic acid molecule which comprises DNA having at least about 80% sequence identity to a DNA molecule encoding a FGF-19 polypeptide. It would require undue experimentation and making a substantial inventive contribution for the skilled artisan to discover how to practice the full scope of Applicants' invention as currently claimed.

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8. Claims 1, 5-7, 14-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 5-7, 14-22 are directed to nucleic acid molecules which have at least about 80% identity to a DNA molecule encoding a FDF-19 polypeptide, or to a DNA molecule encoding the same protein cDNA deposited in an ATCC Deposit. However, the instant specification fails to describe the entire genus of nucleic acids, which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a nucleic acid molecule of SEQ ID NO:1. This nucleic acid molecule is contained within ATCC deposit #209480. The subject matter, which is claimed is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are nucleic acid molecules, which have at least about 80% identity to a DNA molecule encoding a FDF-19 polypeptide, or to a DNA molecule encoding the same protein cDNA deposited in an ATCC Deposit. First, the claims are not limited to a polynucleotide with a specific nucleic acid sequence. The claims only require the polypeptide share some degree of structural similarity to the isolated nucleic acid of SEQ ID NO:1. The specification only describes a polynucleotide having the nucleic acid sequence of SEQ ID NO:1 and fails to teach or describe any other

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polynucleotide, which lacks the nucleic acid sequence of SEQ ID NO:1 and has the activities possessed by the isolated protein. Therefore, there is a lack of guidance or teaching regarding structure and function because there is only a single example provided in the specification and because there is no guidance found in the prior art.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the nucleic acid molecule of SEQ ID NO:1. The specification does not provide a complete structure of those nucleic acid molecules which have at least about 80% identity to a DNA molecule encoding a FDF-19 polypeptide, or to a DNA molecule encoding the same protein cDNA deposited in an ATCC Deposit. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus (those nucleic acid molecules which have at least about 80% identity to a DNA molecule encoding a FDF-19 polypeptide, or to a DNA molecule encoding the same protein cDNA deposited in an ATCC Deposit) because the specification teaches only the one embodiment of SEQ ID NO:1. Therefore, the claims are directed subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

9. Claim 22 is further rejected under 35 U.S.C. 112, first paragraph, for claiming an inoperable process. Briefly, claim 22 is directed to a process for producing a FGF-19 polypeptide by culturing a host cell, which contains a vector comprising the nucleic acid molecule of claim 1, while nucleic acids of claim 1 do not encode the FGF-19 polypeptide of SEQ ID NO:2.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-11 and 13-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 1-4, 9-11, 13-16, 18-22 are vague and indefinite for recitation of "FGF-19 polypeptide". The metes and bounds of the term "FGF-19 polypeptide" cannot be determined from the claim.

12. Claims 1, 5, 7 and 14 are indefinite for reciting "about 80% sequence identity". The metes and bounds of "about 80%" cannot be determined from the claims.

13. Claims 1, 4, 9, 10 and 13 are vague and indefinite in their recitation of limitation "about 23 to about 216 amino acids". Even though the term "about" in a claim is inherently vague and indefinite, its use is appropriate when employed to limit a value which is composed of indefinitely divisible units such as inches, meters, grams and pints, where it is impractical to

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produce an item which has exactly the dimension recited. Even if one could practically produce an item which is exactly 1 inch in length, the length of that item is conditional upon the temperature at which it is measured. However, when defining an invention in terms of indivisible numerical units such as the number of nucleotides in a nucleic acid, the number of amino acids in a polypeptide or the number of legs on a chair or table, the term "about" is unacceptably vague and indefinite since it is practical to employ a term, which possesses the required precision. If, for example, it is Applicant's intension that the claims should encompass a polypeptide of more than a certain amount of acids in length then this is exactly what the claim should recite.

Whereas one would reasonably interpret the term "about one inch" as encompassing any value from 0.90 inches to 1.10 inches one would not know if the term "about 23 to about 216 amino acids" would exclude 22 or 24 to 215 or 217 amino acids.

14. Claim 2 is vague and ambiguous for reciting "the sequence of nucleotide positions". The metes and bounds of "nucleotide positions" cannot be determined from the claim. Further, the claim is indefinite for recitation of "about 464 or about 1111" (for explanations see section 10 of the instant office action.).

15. The scope of the claim 9 cannot be positively interpreted, which makes the claim vague and indefinite. The only limitation of claim 9 is a "nucleic acid molecule encoding a FGF-19 polypeptide, while addition "comprising DNA that hybridizes to the complement" makes the claim confusing.

16. Claims 11 and 13 are indefinite because conditions of "stringent hybridization", which is an important limitation of a claim, are not defined.

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17. Claim 16 is vague and ambiguous because the claim requires that "nucleic acid molecule is operably linked to control sequences" referring to claim 1, while the vast majority of the nucleic acid sequences encompassed by claim 1 do not encode a protein.

18. Claim 22 is indefinite because the claim requires the production of FGF-19 polypeptide using nucleic acids that do not encode a FGF-19 polypeptide.

19. Claims 3, 6, 8, 15, 17-21 are indefinite for being dependent from the indefinite claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Baird et al. (1990, Handbook of Exp. Pharmacology, Chapter 7, 95 (1), pp. 369-419, reference 7 of record in the list of disclosures cited by Applicant).

Claim 9 encompasses any isolated nucleic acid molecule encoding "FGF-19 polypeptide". Without providing hybridization conditions and definition of "FGF-19 polypeptide" any nucleic acid, encoding a fibroblast growth factor would anticipate the nucleic acid of claim 9. Baird et al. teach acidic and basic fibroblast growth factors providing their amino acid sequences. Therefore, a nucleic acid encoding, for example, basic fibroblast growth factor, would anticipate a nucleic acid of claim 9.

Conclusion

21. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. *nc*
March 8, 2002

[Handwritten signature]
JOHN ULM
RECEIVED
MAR 10 2002